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Patent

Attorney Docket No. CMED.10023

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Jerry Y. JONN et al.

Mail Stop: RCE

Application No.: 09/919,877

Group Art Unit: 1616

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Examiner: Frank I. Choi

Title: Absorbable Adhesive Compositions

Confirmation No.: 4857

DECLARATION UNDER 37 C.F.R. §1.132

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Jerry Y. Jonn, hereby declare that:

1. I am an inventor of subject matter claimed in the above-identified patent application. I earned Masters of Science and Ph.D. degrees in polymer chemistry from Cornell University. I have served as Vice President of Research of Closure Medical Corporation since January 2004. Prior to that, I served as Vice President, Internal Product Development and Director, Absorbable Products Research. I have extensive experience with cyanoacrylate monomers, polymers and adhesives.

2. The biocompatible adhesive compositions claimed in the present application include a first monomer species, a second monomer species and a polymerization initiator or accelerator. The monomer species are selected such that the first monomer species has a first polymer absorption rate and the second monomer species has a second polymer absorption rate different from the first polymer absorption rate. The polymerization initiator or accelerator allows polymerization of the monomers to provide

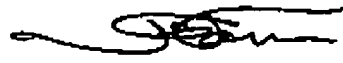
a biocompatible adhesive composition with a polymer absorption rate different from either of the polymer absorption rates of the monomer species.

3. A suitable initiator or accelerator may be selected in light of the present disclosure, in combination with the selection of monomer, to produce a polymer with a desired absorption rate. A screening process utilizing routine experimentation may be used to identify combinations of monomers and initiators or accelerators that possess the desired reaction kinetics and produce a polymer that is absorbed *in vivo* in the desired period of time. Thus, the selection of monomers and initiator or accelerator as claimed permits the monomers selected to polymerize at substantially the same rate so that the adhesive comprises one polymer when polymerized.

4. Previous formulations of cyanoacrylate monomers included initiators to induce polymerization. However, prior formulations or disclosures regarding cyanoacrylate monomers did not specify particular properties such as absorbability possessed by particular combinations of cyanoacrylate monomer species or disclose methods to obtain a polymer in an adhesive composition which has a polymer absorption rate different from either of the polymer absorption rates of the monomer species. In addition, prior disclosures did not recognize problems involving differing polymerization rates when monomers are used with different polymer absorption rates. If different cyanoacrylate monomers are used and the monomers do not react at substantially the same time, the polymerized adhesive will include two different separate polymers, rather than one polymer or, in other words, one polymerized adhesive composition. Thus, the monomer selection and an appropriate initiator or accelerator must be present as claimed to provide the desired adhesive composition. The selection of monomer and initiator as taught in the specification allows for monomers with greatly varying polymerization rates to be used together and still result in a single polymeric adhesive upon polymerization of the first and second monomer species with the initiator or accelerator.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further

that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of application or any patent issued thereon.



Jerry Y. Jonn